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10/518,909

09/01/2005

Braj Bhushan Lohray

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EXAMINER

PALENIK, JEFFREY T

ART UNIT

PAPER NUMBER

4133

MAIL DATE

DELIVERY MODE

10/26/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/518,909

Applicant(s)

LOHRAY ET AL.

Examiner

Jeffrey T. Palenik

Art Unit

4133

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 23 Dec 2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 1-22 are presented and represent all of the claims under consideration.

Priority

This application is the National Stage filing of International Patent Application No. PCT/IN03/00229, filed 25 June 2003. Applicant claims priority to Indian Foreign Application No. 565//MUM/2002, filed 26 June 2002. Examiner finds that Applicant's filing meets the priority requirements and determines the earliest effective U.S. filing date to be 26 June 2002.

Information Disclosure Statement

An Information Disclosure Statements filed 23 December 2004 is acknowledged and has been reviewed.

Specification

The abstract of the disclosure is objected to because of the grammar and syntax. Correction is required. See MPEP § 608.01(b).

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Objections

Claims 1, 6, 7, 17 and 19 are objected to because of the following informalities:
grammar corrections. Appropriate correction is required.

Claim 5 is objected to because of the following informalities: there is no punctuation ending the claim. Appropriate correction is required.

Claims 15 and 17 are objected to because of the following informalities: the symbol "&" is used in lieu of the word "and" (claim 15) and there is a misspelling "si.mvastatin" (claim 17). Appropriate correction is required.

Claim 20 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim in independent form. The instant claim 20 cites coating limitations as optional to the delivery system of claim 1. Since the limitations are not required the claim inherently cites that no further limitation is placed on the preceding independent claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 5, 14 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of the instant claim 5 cannot be precisely determined due to the lack of punctuation at the end of the claim. No period implies open language of the present claim and allows for any number of additional pharmaceutical aids to read into the claim.

The recitation "may also be used for" renders claim 14 unclear. The preceding additional uses to the local treatment of the gastrointestinal tract are undefined.

Claim 16 provides for the use of the delivery system of claim 1, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 16 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd. App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2 and 4-22 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Bar-Shalom et al. (U.S. Patent 5,213,808).

Bar-Shalom et al. teaches a multi-layered article for controlled, pulsatile delivery of an active substance into an aqueous phase wherein the active agent is embedded in a controlled release polymer matrix (Abstract and claim 1). Ethyl cellulose and hydrogenated oils are taught as excipients (e.g. fillers) at column 10, lines 27-33. Claim 12 teaches that at least one of the layers is comprised of a filler such as binders, lubricants or disintegrants, which are further defined (column 10, lines 20-40). Controlled-release polymer matrices (e.g. coatings) such as hydroxypropyl methylcellulose are taught to impact release of a drug, such as immediate release (column 17, lines 24-31) and to contain a water-soluble surface agent (claim 4). The therapeutically active agent is taught to be dispersed or embedded and in a tablet-shaped form (claims 29 and 33) formed by compressing the individual layers (column 18, lines 6-11). A “narrow absorption window” is taught for the therapeutically active agent at lines 48-56 of column 2. Therapeutic classes and agents, such as anti-ulcer agents like ranitidine, are taught (column 7, line 24 to column 9, line 26). Example 4 (column 23) teaches the formulation to contain 426 mg of an active agent (e.g. morphine hydrochloride). The active agent is taught to be floated on gastric fluids (e.g. delivered) for a predetermined, typical range of 1-12 hours, but is also taught to be advantageously delivered 15 minutes following administration (column 2, lines 44-56).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-15 and 17-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bar-Shalom et al. (U.S. Patent 5,213,808).

Bar-Shalom et al. teaches a multi-layered article for controlled, pulsatile delivery of an active substance, as described above. Despite teaching the use of both ethyl cellulose and hydrogenated oils as miscible excipients within the same embodiment, Bar-Shalom teaches no specific ratio (e.g. 95:5 to 30:70) of the former to the other the latter.

However, the adjustment of particular conventional working conditions (e.g. determining result effective amounts of the ingredients beneficially taught by the cited references, especially within the broad ranges instantly claimed), is deemed merely a matter of judicious selection and routine optimization, which is well within the purview of the skilled artisan.

Accordingly, this type of modification would have been well within the purview of the skilled artisan and no more than an effort to optimize results.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey T. Palenik whose telephone number is (571) 270-1966. The examiner can normally be reached on 7:30 am - 5:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-270-2966.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Jeffrey T. Palenik

Patent Examiner



JEFFREY STUCKER
SUPERVISORY PATENT EXAMINER